


PART IX

Human Subject Research: Policies and Forms

**PROVIDER MANUAL
FOR
COMMUNITY MENTAL HEALTH,
DEVELOPMENTAL DISABILITIES AND
ADDICTIVE DISEASES
PROVIDERS
FOR
THE DIVISION OF MENTAL HEALTH,
DEVELOPMENTAL DISABILITIES AND
ADDICTIVE DISEASES**



JULY 2006

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SUBJECT: Protection of Human Subjects

POLICY

The policy of the Department of Human Resources is to assure the protection of the rights of human subjects in research activities that are conducted in association with the Department. The Department will assure subjects' rights by following the policies and procedures contained in 45 CFR, Part 46, Protection of Human Subjects; 21 CFR, Part 50, Protection of Human Subjects; and 21 CFR, Part 56, Institutional Review Boards. The Department is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. A Departmental sponsor is designated when the research is not conducted by an agent of the Department.

A. Authority

45 CFR, Part 46, AProtection of Human Subjects
21 CFR, Part 50, AProtection of Human Subjects
21 CFR, Part 56, AInstitutional Review Boards

B. References

O.C.G.A. § 50-18-101 AUse of Confidential, Classified, or Restricted Records for Research, Limitations

DHR Directive AConfidentiality of and Access to Records

C. Applicability

This policy and related procedures apply to research that is conducted either by the Department or is sponsored by the Department and involves human subjects. Applicability is not limited to federally sponsored projects.

D. Definitions

Research ≡ means a systematic investigation designed to develop or contribute to generalized knowledge. Routine program evaluation is excluded under this definition.

Human subject ≡ means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information.

Identifiable private information ≡ means any information about an individual's behavior that: occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, **or** has been provided for specific purposes and which the individual can reasonably expect not to be made public (e.g., a medical record), **and** the information is individually identifiable (i.e., the identity of the individual is or may be ascertained by the investigator or associated with the information).

Conducted by the Department ≡ means any research activity that is conducted by an employee of the Department or is funded by the Department.

Sponsored by the Department ≡ means any research activity which requires the support of the Department for granting access to subjects or information. A sponsor is an employee of the Department who assumes certain responsibilities for a research project.

E. Responsibilities

1. It is the responsibility of the Commissioner to establish and maintain an Institutional Review Board that is competent to assure the protection of the rights of human subjects by appointing members according to the policies listed in 45 CFR, Part 46.107, AIRB Membership. Each member will receive orientation to the Board and will participate in a program of continuing education to maintain skills and knowledge. Each member's home division/office is responsible for supporting the activities of the appointed member.
2. It is the responsibility of the Director of the Office of Regulatory Services to provide staff support to the Board by appointing an Executive Secretary and by supporting the activities of that position.
3. It is the responsibility of the DHR Institutional Review Board to assure the rights of human subjects by following the policies and procedures written in 45 CFR, Part 46; and 21 CFR, Parts 50 & 56.
4. It is the responsibility of each division and office to ensure that all research involving human subjects conducted or sponsored by the division/office is approved by the DHR Institutional Review Board. When the research involves access to confidential information and is conducted by a departmental employee or agent, the investigator's division or office is responsible for following the provisions indicated in laws, rules, regulations, etc., concerning access to and release of the information held in confidence.
5. It is the responsibility of the Board to issue procedures (PRO7901) to implement this policy. The procedures include a manual: A Guidance to Researchers Using Human Subjects (MAN7901).
6. It is the responsibility of the researcher to follow the procedures contained in the manual: A Guidance to Researchers Using Human Subjects.
7. It is the responsibility of the departmental sponsor to assure that the research project does not have a negative impact on the provision of service that is being offered. The sponsor is

aware of problems and adverse findings during the conduct of the project and apprises the Board of these events. When the research involves access to confidential information, the sponsor assures that all provisions of applicable laws, rules, regulations, etc. are followed concerning the release of and access to the confidential information.

F. History

Revision of Georgia Department of Human Resources Policy, A Protection of Human Subjects, POL7901, effective 9/30/98.

G. Evaluation


The assurance of rights of human subjects of research conducted by or sponsored by the Department is evaluated by the following methods:

1. On-site assessments are made by DHR staff. When the principal investigator of a project is not a DHR employee and the Board feels that there is significant risks to subjects, the DHR sponsor may be requested to perform an on-site assessment of the project. At other times, Board members may randomly select projects for scheduled or unannounced review. A written summary of these visits is kept for three years.
2. The FDA periodically performs an on-site survey of compliance with federal regulations. Reports of these surveys are kept on file for three years.
 1. An annual review is performed each March to assess any reports from departmental sponsors, any report of breaches of confidentiality, adverse events, or complaints. At the same time, a management information summary is compiled by the executive secretary of actions by the Board for the previous 12 months, including a report of timeliness of actions.

H. Authentication

Audrey W. Horne
Commissioner

2/9/00
Date

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SUBJECT: Protection of Human Subjects

PROCEDURE

1. Institutional Review Board:

1.1. Board membership

The Review Board consists of at least eight members with varying backgrounds to promote complete and adequate review of research activities conducted or sponsored by the department. Members are appointed to meet the following representative criteria: a) two medical doctors who have training and experience in a medical field sufficient to be able to assess medical risks; b) a person who has training and experience in the conduct of scientific investigations; c) a person whose primary concern is not in the area of scientific investigation; d) a legal professional who has experience with the types of issues confronted by the Department and its consumers; e) a person who is not, and whose immediate family is not, affiliated with the Department except as a member of this Board; and, f) a person who has training and experience in working with the consumers of the Department. Additionally, the Board should include diverse membership with regard to race, gender, and cultural backgrounds and shall include persons knowledgeable of institutional commitments and regulations and standards of professional conduct and practice.

Members are nominated by Division/Office Directors and appointed by the Commissioner for staggered two-year terms. Alternate members may be appointed. Alternates are nominated and appointed in the same manner as primary members and serve two-year-terms. They have the same representative capacity as primary members for whom they serve as alternates. An alternate member cannot replace a primary member at a convened meeting unless he/she has received and reviewed the same material that the primary member has received or would have received. An alternate has no vote if the member for whom they are an alternate is present.

There is a chairperson and vice-chairperson who are elected by the members of the Review Board for a term of two years. A representative from the Department's Office of Regulatory Services serves as permanent Executive Secretary of the Board.

1.2. Meetings of the Board

Meetings of the Review Board are scheduled to ensure timely review of all projects. A majority of the membership constitutes a quorum, including at least one member whose primary concerns are in the nonscientific area. A majority vote is required for approval of a motion. If a quorum is interrupted during the proceedings, actions on studies are suspended until a quorum is again attained. All projects approved using the expedited review process are included on the agenda of the next convened meeting of the Board. Votes are recorded and reported numerically. Meetings are public and open to any interested party. Information regarding time and location of meetings may be obtained from the Executive Secretary.

1.3. Functions of Chairperson

The Chairperson, the Vice-Chairperson, or a designee presides at all convened meetings of the Board. Additionally, the Chairperson is responsible for:

- a. reviewing all applications and determining (with the Review Coordinator) if they meet the criteria for approval without detailed review or for expedited review;
- b. assigning a Review Coordinator for each project to be reviewed;
- c. reviewing and approving agenda prior to meetings of the Board;
- d. providing members with available information to assist them in carrying out the functions of the Board;
- e. assuring that members have background and training to assure competent functioning of the Board; and,
- f. serving as a liaison between the Board and the Office of Human Research Protections, the Food and Drug Administration, and other Federal Agencies.

1.4. Functions of the Review Coordinator

After the Chairperson performs a cursory review of an application, he or she assigns it to a Board member who serves as the Review Coordinator for the project until it is closed by the Board. The Chairperson makes a recommendation regarding the type of review (see section 4.1. of the manual MAN7901). If the Review Coordinator disagrees with the recommended type of review, he or she contacts the chairperson and they resolve the issue. The Review Coordinator is responsible for a detailed initial review, for communication with the investigators, and for tracking the project until it is closed. Specifically, the responsibilities are:

- a. upon receipt of the application, performs a detailed review to identify issues, missing information, unanswered questions, or other needed information;
- b. contacts the investigator, prior to application being placed on the agenda, to resolve the identified issues, missing information, etc.
- c. notifies the chairperson when the application is ready to be placed on the meeting agenda;
- d. presents the application at the convened meeting of the Board; (The presentation generally lasts a maximum of 5 minutes and identifies, at a minimum: (1) the involvement of DHR, (2) the purpose and design of the study, (4) subject information - vulnerable, how many, where, how recruited, etc., and, (5) issues for discussion.)
- e. after the Board members discuss the issues, including any other issues identified by other Board members, recommends a decision to either table the application, approve it with conditions, or approve it with no conditions;
- f. writes a detailed description of the presentation, discussion, and decisions made at the Board meeting regarding the application and forwards the description to the Executive Secretary and Chairperson within two working days of the meeting;
- g. receives (from the Executive secretary) all correspondence regarding the project and responds appropriately;
- h. co-signs with the Executive Secretary, all correspondence regarding the project;
- i. oversees the continuing review process including timely notification of the investigators, and functions a, b, c, d, e, and f, stated above, as they relate to the continuing review.

1.5. Functions of the Executive Secretary

The Executive Secretary is responsible for:

- a. providing necessary staff assistance, and making recommendations to the chairperson;
- b. in conjunction with the Review Coordinators, receiving and issuing all communications with applicants;
- c. in conjunction with the Review Coordinators, recording and publishing minutes of the meetings of the Board;
- d. communicating with Board members, including scheduling meetings;
- e. maintaining records;
- f. in conjunction with the Review Coordinators, insuring timely continuing reviews of all projects, including notifying investigators when reports are due;
- g. maintaining the "Project Status Form" for each project and the associated database; and,
- h. assuring that a quorum is met and maintained throughout the proceedings at all convened meetings of the Board.

1.5. Record Keeping

The Executive Secretary maintains adequate documentation of the Board's activities, including the following:

- a. copies of applications reviewed, including all attachments, progress reports submitted by investigators, statements of significant new findings provided to subjects, and reports of adverse events;
- b. minutes of IRB meetings which are sufficient in detail to show attendance at meetings, actions taken by the IRB, the vote tally on all actions, the basis for requiring changes in or for disapproving applications, and a written summary of discussion of issues and their resolution;
- c. records of continuing review activities;
- d. copies of all correspondence; and,
- e. a list of Board members identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions to Board deliberations, and a description of each member's affiliation with the Department.

These records are retained for at least three years, except that all records related to research that is conducted will be kept for at least three years after the completion of the research project.

These records are available for inspection and copying by authorized persons during normal business hours. They are housed in the Office of Regulatory Services.

2. Auxiliary Review Committees

Institutions or divisions within the Department which conduct or support a significant amount of research may elect to form an internal committee for oversight of research activities within their organizational unit. The functions of any internal committee may supplement the functions and responsibilities of the Department's Institutional Review Board, but will not be a substitute for any required activities of the Board.

3. Application for Approval and Guidance to Researchers

This information is contained in the "Guidance to Researchers Using Human Subjects Manual." See attached Manual, Directive # [MAN7901](#).

A. History

Replaces PRO7901, effective date of 9/30/1998.

B. Proponency

Office of Regulatory Services
Executive Secretary of the IRB
Phone: (404) 657-5700

C. Attachments:

1. Continuing Review Form
2. Project Status Form

IRB Study Number_____

2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

CONTINUING REVIEW FORM

Title of Research:

Approval Period: From_____ To_____

(NOTE: Any data collected before the approval date or after the end date shown above is not covered by IRB approval. If the project is not completed by the end date, this form must be completed and submitted to the Board in order to receive continuing approval for the project. The form must be received by the Board **at least six weeks prior to the end date** in order to assure uninterrupted approval. Complete this form at the conclusion of the project and send it to the IRB)

1. What is the stage of the project? (Circle One)
 - a. Initial preparation
 - b. Data Collection
 - c. No further involvement with subjects
2. Have any subjects dropped out or been withdrawn from the study?
YES NO (If yes, attach explanation.)
3. Since the project was approved, have all changes been submitted to the Board for review and approved?
YES NO (If no, project activities must stop until approval is granted.)
4. Attach to this form a summary description of the experiences of subjects who have been involved with the project. Include information about benefits, adverse events, problems, and complaints, and any results to date.
5. Have all approved procedures been followed?
YES NO (If no, attach an explanation.)
6. Has the project resulted in any risks to subjects that were not identified in the approved protocol?
YES NO (If yes, attach an explanation.)
7. Is there any further information that should be communicated to the Board?
YES NO (If yes, attach communication.)
8. Please attach a copy of the consent form that you are currently using.

This completed form and its attachments are an accurate report of the progress and status of the project.

Signature of Investigator

Date

Signature of Sponsor

Date

DHR Institutional Review Board
Number _____
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

IRB Study

PROJECT STATUS FORM

Title of Research:

Board Review Date: _____ Disposition _____

Board Review Date: _____ Disposition _____

Approval From: _____ To: _____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date: _____ Disposition _____

Board Review Date: _____ Disposition _____

Approval From: _____ To: _____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date: _____ Disposition _____

Board Review Date: _____ Disposition _____

Approval From: _____ To: _____

Communication from Investigator:

Type: _____

Date: _____

Type: _____

Date: _____

Type: _____

Date: _____


Type: _____

Date: _____

Other Information:

Project Completion Date: _____

IRB Closed Date: _____

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GUIDANCE TO RESEARCHERS USING HUMAN SUBJECTS

MANUAL

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1. Introduction

The Department of Human Resources maintains an Institutional Review Board which is charged with assuring that the rights of human subjects of research conducted or sponsored by the Department are protected as outlined in federal and state policies and regulations. The Board is guided by the ethical principles set forth in the publication: “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.”

All research projects that involve human subjects must be submitted to the Board and approved by the Board prior to their initiation. These and other requirements for continuing contacts between the investigators and the Board are enumerated in this manual. The Board has the

authority to suspend or terminate approval for research projects when certain requirements are not met. Approval of research projects is based on the determination that all aspects of the project are in accordance with the procedures that are outlined in this manual and other applicable regulations and considerations.

Insuring the rights of human subjects of research is a collaborative effort of all those persons who are involved with the research project. The procedures that are outlined in this manual constitute the minimum framework to assure that subjects' rights are protected. It is the Board's responsibility to assess whether or not these minimum standards are met based on what is submitted to them. It is in the conduct of the research project, however, that the standards are implemented. The process of protecting subjects' rights, then, hinges on the performance of the investigators as they carry out the project.

It is hoped that the intent of these procedures will be helpful as a guide to investigators as they make the innumerable decisions necessary to conduct a research project. If there are questions, the Board may be reached at:

Georgia Department of Human Resources
Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, Georgia 30303-3167
(404) 657-5700

2. Application Process

2.1. Who should apply for approval

Approval must be obtained for all research involving human subjects that is conducted by or sponsored by the Department. These terms are defined within the policy statement. Approval must be obtained prior to any involvement of the subjects. The approval by the Board is limited to a 12-month period and must be renewed annually to continue the involvement of subjects. Researchers must have no involvement with subjects unless they have current approval from the Board.

2.2. Application Procedures

Applications for approval are filed with the Executive Secretary of the Board in the Office of Regulatory Services. Applications are submitted using the attached two forms: "Application for Approval of Research Using Human Subjects," and "Format Guide for Consent Form."

Applicants are to follow the instructions listed on the forms. Note that the information that appears in bold print should be replicated by the applicant on both the application form and the consent form. Note that the information that is italicized is to be substituted by the applicant with information that applies to the research project under consideration. The grant application or other description of the project may be submitted, but the required information must be submitted on the forms as indicated. No application will be considered until all the information is received by the Board. A complete application package includes: 1) a completed and signed "Application for Approval of Research Using Human Subjects;" 2) the proposed consent form; 3) any questionnaires or other written instructions to be given to subjects; and 4) an investigator's brochure, if the study is conducted under the Investigational New Drug regulations.

Note that the application should be submitted at least six weeks prior to the desired start time. Note also that no activity may begin until approval from the Board is received.

3. Informed Consent

Except as provided elsewhere in this directive, no investigator may involve a human subject in a research project unless the investigator has obtained the legally effective informed consent of the subject or the subject's guardian. An investigator shall seek such consent only under circumstances that provide the prospective subject or the guardian sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject and/or the guardian shall be in language that is understandable to the subject or guardian. No informed consent shall contain any language that waives or appears to waive any of the subject's legal rights or appears to release the investigator, the sponsor, or the institution or its agents from liability for negligence.

3.1. Elements of Informed Consent

The minimum elements of informed consent are found on the form that is attached to this procedure: "Format Guide for Consent Form." When appropriate, one or more of the following elements of information shall also be provided to each subject as part of the consent form:

- a. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- c. any additional costs to the subject that may result from participation in the research;
- d. all appropriate alternatives to participation, including nonparticipation;
- e. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- f. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- g. the approximate number of subjects involved in the study;
- h. if the design includes treatment and control groups (and/or placebo control groups), statements that describe how the subject will be assigned to groups; and,
- i. for certain subjects, including patients in any institution of the Division of Mental Health, Mental Retardation, and Substance Abuse, a statement from the subject's attending physician that the subject understands the informed consent and is competent to give consent for participation in the study.
- j.

3.2. Situations When Written Consent Not Required

The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the Board finds and documents that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: public benefit of service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and, the research could not practicably be carried out without the waiver or alteration. Projects that are conducted under this waiver must meet the provisions of [O.C.G.A. §15-18-101](#) and related DHR Directives. In order for this waiver to be considered, the investigator must submit, along with the other requirements for application, the agreement concerning confidentiality of records and the statement from the appropriate official that the proposed project meets the requirements of O.C.G.A. §15-18-101 and other DHR Directives. The Board may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the Board finds and documents that:

1. The research involves no more than minimum risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The consent cannot practicably be obtained and the research could not practicably be carried out without the waiver or alteration; and,

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The Board may waive the requirement for a signed consent form (but not the requirement for informed consent) in situations where the only record linking the subject and the research would be the signed consent document or in situations, such as phone interviews, where a signature is not feasible. An example would be an anonymous mailed questionnaire. In this situation, a cover letter could contain the elements of informed consent and a signature of the subject would not be required.

There are certain other “emergency” situations, detailed in [21 CFR, 50.23](#) & [24](#), where an intervention may occur without prior informed consent.

4. Approval Process

Application approval or disapproval will be communicated to the investigator and sponsor in writing. If the Board decides to disapprove an application, it will include in its written notification a statement of the reasons for its decision and will give the investigator an opportunity to respond in person or in writing. Should an application be disapproved, no further processing of the application will take place until the Board’s concerns are met and a positive vote is obtained.

4.1. Types of Review and Criteria

The Board may follow one of three procedures for review of an application, depending on the characteristics of the project. The types of review and the criteria for each type are listed below.

4.1.1. Approval Without Detailed Review

Applications for projects in which the only involvement of human subjects is in categories that are described below may be approved by the Chairperson without further review. The categories are:

- a. research conducted in established or commonly accepted education settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;
- b. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless 1) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and 2) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation;
- c. research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under subparagraph 2. above, if 1) the human subjects are elected or appointed public officials or candidates for public office or 2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;
- d. research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available

or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects;

- e. research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: 1) public benefit or service programs, 2) procedures for obtaining benefits or services under those programs, 3) possible changes in or alternatives to those programs or procedures, or 4) possible changes in methods or levels of payment for benefits or services under those programs; (For projects in this category, the investigator must submit, along with the other requirements for application, the agreement concerning confidentiality of records and the statement from the appropriate official that the proposed project meets the requirements of and other DHR Directives.)
- f. taste and food quality evaluation and consumer acceptance studies if: 1) wholesome foods without additives are consumed, or 2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

4.1.2. Expedited Review

For applications for projects meeting the below described eligibility requirements for expedited review, the review may be performed by the chairperson or by one or more Board members, designated by the Chairperson, who are experienced reviewers. In reviewing the research, the reviewers may exercise all the authorities of the Board except the reviewers may not disapprove the research. The reviewers may approve the application, or they may require modifications and grant approval once these modifications have been made. If they do not approve the application, it will be forwarded to the Board for a full Board review.

The eligibility requirements for expedited review are as follows: the application represents minor changes in a currently approved project, or the research is found to involve no more than minimum risk to the subject and appears on the list below: (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

- a. collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction;
- b. collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;
- c. recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice (This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's

privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible

range [for example, x-rays, microwaves]);

- d. collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant;
- e. collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- f. voice recordings if made for research purposes such as investigations of speech defects;
- g. moderate exercise by healthy volunteers;
- h. the study of existing data, documents, records, pathological specimens, or diagnostic specimens;
- i. research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the project will not involve stress to subjects;
- j. research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

4.1.3. Full Board Review

Full Board review is required for all eligible projects that do not meet the criteria for either of the two above categories of review.

4.2. Review Criteria

In order to approve a research project, the Review Board will determine if all of the following are met:

- a. risks to subjects are reasonable in relation to any anticipated benefits to subjects and the importance of the knowledge to be gained;
- b. risks to subjects are minimized by using procedures that are consistent with sound research design, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
- c. selection of subjects is equitable;
- d. appropriate measures are in place to obtain and document the prior informed consent of the subjects or the subjects' guardians;
- e. there are adequate provisions for protecting the confidentiality of data which identify individual subjects; and
- f. there are adequate provisions for monitoring the collected data to ensure the safety of subjects and to protect their privacy by maintaining anonymity or confidentiality of the data.

For research projects that involve the participation of vulnerable subjects, there are specific requirements contained in the federal regulations. Compliance with these regulations will be assessed by the Board when a project involves any of these groups of subjects. The types of subjects and the associated federal regulation(s) are listed below.

Fetuses, pregnant women, and human in vitro fertilization - [45 CFR 46.201-46.211](#)

Prisoners - [45 CFR 46.301-46.306](#)

Children - [45 CFR 46.401-46.409](#)

4.3. Continuing Review

Approval to conduct a project may be granted for a period of no more than one year. If the project is not completed by the end of the approved period, the investigator must apply for a continuation of the approval. The length of the approval period and the extent of continued review will be determined by the Board at the time of approval and will be communicated to the investigator. The Board will contact the investigator prior to the end of the approved period to solicit the required information in order to review the project for continued approval. The information requested on the "Continuing Review Form" is compiled at this time by the investigator and submitted to the Board. The Board considers the request and notifies the investigator of the decision.

4.3.1. Frequency and Extent Considerations

The length of time of approval for each project will be based on a consideration of the vulnerability of the subject population and the extent of risks to subjects. Special attention will be given to projects involving new procedures or treatments and projects involving placebo control groups. The following is a frequency guideline for approval periods:

- a. New drug trials - 6 month approval period;
- b. Projects involving pregnant women, children, or other vulnerable populations - 9 to 12 month review period; and
- c. Projects involving minimal risks to subjects - 12 month approval period.

The extent of the continued review will be determined by an assessment of the vulnerability of the subject population, the extent of risks to the subjects, and a consideration of other factors of the research administration and design. For example, for projects for which the investigator is not a DHR employee, the Board may require the DHR sponsor to perform an on-site visit of the project to determine compliance with the procedures stated in this manual. Another example is that for projects for whom the sponsor and the investigator are the same person, an uninvolved person may be asked to perform an on-site monitoring of the project.

4.3.2. Suspension or Termination of Projects

The Review Board may suspend or terminate approval of research that is not being conducted in accordance with requirements for the protection of human subjects and any research associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the Board's action and will be reported promptly to the investigator, to the Division or Office of the Department of Human Resources, and, if appropriate, to the U. S. Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and other organizations.

If it is determined after the fact that any of these procedures were not followed in the course of the research project, then written notification of such findings will be sent to the investigator and all appropriate organizations, including the institution with which the investigator is affiliated.

The continuation of a research project after the expiration of the Board's approval is a violation of federal regulations. If the Board's approval has expired, research activities must stop. No new subjects may be enrolled in the project. If the investigator is actively pursuing renewal of approval with the Board and the Board believes that there are no overriding safety or ethical concerns, then the Board may exercise flexibility in allowing the project to continue for a brief time needed to complete the review process.

When study approval is terminated by the Board, in addition to stopping all research activities, any subjects currently participating should be notified that the study has been terminated. Procedures for withdrawal of enrolled subjects should consider the rights and welfare of the subjects. If follow-up of subjects for safety reasons is permitted/required by the Board, the subjects should be so informed and any adverse events or outcomes should be reported to the Board.

5. Responsibilities of Investigators

It is the responsibility of the investigator to design the project in such a way that minimizes risks to subjects and to continuously monitor the activities of the project to assure that the risks remain at a minimum. It is the responsibility of the investigator to report in writing the following information to the Board:

- a. any reports requested by the Board, including continuing review information;
- b. any changes in the project's protocol, including a change of DHR Sponsor; and
- c. adverse events associated with the project.

Any proposed changes in previously approved projects must be approved by the Board and cannot become effective prior to being approved. Consideration of changes will be accomplished in the manner described for initial approval of applications.

In addition to reporting to the Board, the investigator must report adverse events as required to the Food and Drug Administration and must indicate to the Board such notification. The Board will acknowledge these reports in writing and will indicate one of the following: 1) the Board will review the report at the next meeting and the project may continue until a formal Board action is taken; or 2) the project must be discontinued immediately. The chairperson of the Board has the authority to make the decision concerning which course of action will be followed.

6. Appeals

A decision to disapprove a research project may be appealed by submitting a written request for reconsideration by the Review Board, including any additional data pertinent to the decision. Upon receipt, the request and any

related documents will be conveyed to the Board for reconsideration. The reconsideration will be accomplished in the manner described for initial review. A negative decision by the Board cannot be reversed except by a vote of Board members.

DHR Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

**APPLICATION FOR APPROVAL OF RESEARCH
USING HUMAN SUBJECTS**

Page 1 of 2.

Title of Research Project:

Principal Investigator	* DHR Sponsor
Name:	Name:
Position:	Position:
Affiliation	Affiliation:
Address:	Address:
Telephone Number:	Telephone Number:
**Signature:	*Signature:

*Required if the principal investigator is not a DHR employee.

**Your signature indicates that you have read the DHR's "Guidance to Researchers Using Human Subjects Manual," and that you understand and agree to follow the procedures specified in the Manual. Your signature further attests that you assume responsibility for assuring that all aspects of and personnel involved with this project follow the specified procedures.

Date you would like approval for project to begin: _____
(Should be at least 6 weeks from date of submission to IRB)

Date you anticipate last contact with subjects: _____

Date you anticipate completion of project: _____

PLEASE COMPLETE THE APPLICATION AND FORWARD THIRTEEN COPIES

OF THE APPLICATION AND ATTACHMENTS TO THE DHR INSTITUTIONAL REVIEW BOARD

**APPLICATION FOR APPROVAL OF RESEARCH
USING HUMAN SUBJECTS**

Respond to all ten statements listed below. Type each statement (in bold) and add your response for each number. If a statement does not apply, write “not applicable.” Applications should not be over five pages. Do not send “method sections” or grant proposals. Do not respond to any statement with “see attachments.”

1. *Research Abstract*

State rationale and research question or hypothesis. Clearly explain why you are conducting this research, what are the anticipated benefits, and what is the importance of the knowledge to be gained.

2. *Design*

Identify your research design and specific factors or variables, conditions, or groups in your study and any control conditions. Indicate the number of subjects assigned to each group, how they will be assigned to groups, and describe plans for data analysis.

3. *Research Subjects*

a. Number and description of subjects

Describe subject characteristics (age, gender, diagnosis, etc.).

b. Method of selection/recruitment of subjects **Attach copies of any fliers, advertisements, etc. that will be used.**

c. Compensation

Describe any incentives or compensation offered for participation.

4. *Procedures Summary*

State in chronological order what the subjects are expected to do, or describe what procedures the subjects will be involved with. If deception is necessary, justify and describe. Submit debriefing procedures that include an explanation to subjects about how and why they were deceived, as well as providing an educational summary.

5. *Materials*

List, in sequence, all questionnaires and/or tasks to be given to subjects. Attach a labeled copy of all written instruments to each copy of this application. Attach copies of the investigator's brochure, if the study is conducted under the Investigational New Drug regulations.

6. *Confidentiality Assurances*

If the results of participation are not public or anonymous, then describe how confidentiality of information will be maintained. Describe how long information, data, or other items will be kept. Describe destruction techniques. If data, information, or other items are to be kept indefinitely, so state, and give purpose of retention and method to assure continued confidentiality.

7. *Risks Summary*

- a. Current Risks** Describe any psychological, social, legal, economic, or physical discomfort, stress, or harm that might occur to subjects as a result of their participation in this research. Describe how these risks will be held to the absolute minimum.

- b. Future Risks** Describe any future risks that subjects may experience as a result of their participation in this research. Describe how these risks will be kept at an absolute minimum.

8. *Benefits*

a. To Subjects

Describe any potential beneficial effects that participation in this research might have for subjects.

b. To Humankind

Identify any potential benefits that humankind in general will gain from this research.

9. *Vulnerable Subjects*

If vulnerable subjects (including minors) are involved, outline procedures that will be used to obtain their agreement to participate (in addition to informed consent from parents or guardians). Describe any other procedures that will be used to safeguard the rights of vulnerable subjects.

10. *Informed Consent*

Describe the procedure that will be used to obtain legally effective informed consent from subjects. Attach copies of the form to be used.

FORMAT GUIDE FOR CONSENT FORM

(This guide contains the minimum elements that are necessary for approval of research using human subjects . Additional information may be required in some circumstances. Refer to the “Guidance to Researchers Using Human Subjects Manual” for more information. The language in the form should be understandable to the subjects and be stated in the first person.)

I agree to participate in the research titled (*title of research*) which is being conducted by (*investigator’s name, title, affiliation, phone number*). I understand that my participation is entirely voluntary. I understand that I can withdraw my consent at any time (without penalty *OR describe penalty*) and can have the results of my participation, to the extent that it can be identified as mine, returned to me, removed from the record, or destroyed.

The following points have been explained to me:

1. The reason for the research is (*give a short justification*).
2. The benefits that I may expect for the research are (*list specific benefits to the subject*).
3. **The procedures are** (Describe what will happen to the subject, including the time, place, and duration. Describe any questionnaires that are used. In studies involving experimental treatments, identify the parts that are new or experimental, and indicate how they differ from other procedures that could be followed. If deception is necessary, state: **“In order to make this study a valid one, some information about my participation will be withheld until after the study.”**)
4. The discomforts or stresses that I may face during this research are (*List discomforts or stresses or, if none are foreseen, then include this statement: “No discomforts or stresses are foreseen.”*)
5. **Participation involves the following risks** (List all potential physical, psychological, social, or legal risks. Also list the steps to be taken if harm should come to the subject, including any availability of medical treatment or referrals if needed. If no risks are foreseen, then include this statement: **“No risks are foreseen.”**)
 - The results of my participation will not be confidential, but (*describe any controls on access to data*). (*OR*)
 - The results of my participation will be anonymous. (*OR*)
 - The results of my participation will be confidential, and will not be released in any individually identifiable form without my prior written consent, unless otherwise required by law. (*Describe any special procedures regarding anonymity or confidentiality. For example, describe how data will be stored, how identifiers will be removed, give erase dates for tapes, give date data will be destroyed, etc. If data, tapes, or other items are to be kept indefinitely, so state, with purpose for retention, and method to assure confidentiality.*)
7. The investigator will answer any questions I have about the research, now or during the course of the study.
8. I may contact (*Investigator’s IRB - name of contact person, phone number and address*), who is not directly involved with this research, if I have any questions about my rights as a subject in this study.

(Under some circumstances the following assurance is necessary: I have examined (name of subject) and found him/her to be competent to give informed consent for participation in this study.

Printed Name of Physician_____

Signature _____ *Date* _____

Signature of Investigator

Date

Signature of Subject

Date

PLEASE SIGN BOTH COPIES OF THIS FORM. KEEP ONE COPY AND RETURN THE OTHER TO THE INVESTIGATOR.

PROTECTION OF HUMAN SUBJECTS

DHR Institutional Review Board
2 Peachtree Street, NW, Suite 32-415
Atlanta, GA 30303-3167
(404) 657-5700

IRB Study Number _____

CONTINUING REVIEW FORM

Title of Research: _____

Approval Period:
From _____ To _____

(NOTE: Any data collected before the approval date or after the end date shown above is not covered by IRB approval. If the project is not completed by the end date, this form must be completed and submitted to the Board in order to receive continuing approval for the project. The form must be received by the Board **at least six weeks prior to the end date** in order to assure uninterrupted approval. Complete this form at the conclusion of the project and send it to the IRB)

1. What is the stage of the project? (Circle One)
 - a. Initial preparation
 - b. Data Collection
 - c. No further involvement with subjects
2. Have any subjects dropped out or been withdrawn from the study?
YES NO (If yes, attach explanation.)
3. Since the project was approved, have all changes been submitted to the Board for review and approved?
YES NO (If no, project activities must stop until approval is granted.)
4. Attach to this form a summary description of the experiences of subjects who have been involved with the project. Include information about benefits, adverse events, problems, and complaints, and any results to date.
5. Have all approved procedures been followed?
YES NO (If no, attach an explanation.)
6. Has the project resulted in any risks to subjects that were not identified in the approved protocol?
YES NO (If yes, attach an explanation.)
7. Is there any further information that should be communicated to the Board?
YES NO (If yes, attach communication.)
8. Please attach a copy of the consent form that you are currently using.

This completed form and its attachments are an accurate report of the progress and status of the project.

Signature of Investigator

Date

Signature of Sponsor

Date

Protection of Human Subjects

DHR Institutional Review Board
 2 Peachtree Street, NW, Suite 32-415
 Atlanta, GA 30303-3167
 (404) 657-5700

PROJECT STATUS FORM

IRB Study Number_____

Title of Research:

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Request for continuing approval Mailed: _____ Received: _____

Board Review Date:_____ Disposition _____

Board Review Date:_____ Disposition _____

Approval From:_____ To:_____

Communication from Investigator:

Type: _____ Date: _____

Type: _____ Date: _____

Type: _____ Date: _____

Type: _____ Date: _____

Other Information: _____

Project Completion Date: _____

IRB Closed Date: _____

DHR Institutional Review Board

2 Peachtree Street, NW, Suite 32-415

Atlanta, GA 30303-3167

(404) 657-5700

**APPLICATION FOR APPROVAL OF RESEARCH
USING HUMAN SUBJECTS**

Title of Research Project:

Principal Investigator	* DHR Sponsor
Name:	Name:
Position:	Position:
Affiliation	Affiliation:
Address:	Address:
Telephone Number:	Telephone Number:
**Signature:	*Signature:

*Required if the principal investigator is not a DHR employee.

**Your signature indicates that you have read the DHR's AGuidance to Researchers Using Human Subjects Manual² and that you understand and agree to follow the procedures specified in the Manual. Your signature further attests that you assume responsibility for assuring that all aspects of and personnel involved with this project follow the specified procedures.

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**PLEASE COMPLETE THE APPLICATION AND FORWARD NINE COPIES
OF THE APPLICATION AND ATTACHMENTS
TO THE DHR INSTITUTIONAL REVIEW BOARD**

DHR Institutional Review Board

2 Peachtree Street, NW, Suite 32-415 **APPLICATION FOR APPROVAL OF RESEARCH**

Atlanta, GA 30303-3167

(404) 657-5700

USING HUMAN SUBJECTS

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Georgia Department of Human Resources Institutional Review Board

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- 5. Participation involves the following risks (List all potential physical, psychological, social, or legal risks. Also list the steps to be taken if harm should come to the subject, including any availability of medical treatment or referrals if needed. If no risks are foreseen, then include this statement: ANo risks are foreseen.)**
- 6. The results of my participation will not be confidential, but (describe any controls on access to data). (OR) The results of my participation will be anonymous. (OR) The results of my participation will be confidential, and will not be released in any individually identifiable form without my prior written consent, unless otherwise required by law. (Describe any special procedures regarding anonymity or confidentiality. For example, describe how data will be stored, how identifiers will be removed, give erase dates for tapes, give date data will be destroyed, etc. If data, tapes, or other items are to be kept indefinitely, so state, with purpose for retention, and method to assure confidentiality.)**
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(Under some circumstances the following assurance is necessary: I have examined (name of subject) and found him/her to be competent to give informed consent for participation in this study.

Printed Name of Physician_____

Signature_____ **Date**_____

Signature of Investigator **Date**

Signature of Subject **Date**

PLEASE SIGN BOTH COPIES OF THIS FORM. KEEP ONE COPY AND RETURN THE OTHER TO THE INVESTIGATOR.